

REMARKS

In the Office Action under reply, claims 68-92 were rejected on the following grounds:

1. claims 68-87 under 35 U.S.C. § 112, first paragraph;
2. claims 68, 73, 74, 79-82, and 84-87 under 35 U.S.C. § 102(e) as anticipated by Carson et al. (U.S. Patent No. 6,270,780);
3. claims 68-92 under 35 U.S.C. § 103(a) as obvious over Carson et al.;
4. claims 68-91 under 35 U.S.C. § 103(a) as obvious over Ashida (JP 4093288410 A).

With the concurrent filing of the Request for Continued Examination for this matter, applicants respectfully request that the Examiner reverse the finality of the rejection pursuant to 37 C.F.R. § 1.114 and consider the claim amendments set forth above as well as the arguments set forth below, both of which serve in part to address the rejections from the Office Action under reply.

THE CLAIM AMENDMENTS

With the present amendment, claims 88-91 have been canceled.

The remaining independent claims, claims 68 and 92 have been amended to recite a pharmaceutical formulation for the treatment of inflammatory skin conditions, disorders, and diseases (claim 68) or for inhibiting cellular events associated with tumor initiation, promotion, and progression (claim 92), comprising a therapeutically effective concentration of an active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs, and analogs thereof, and combinations of any of the foregoing, wherein the pharmaceutical formulation is a microemulsion for parenteral administration. Support for the recitation that the subject matter of the oral or parenteral resveratrol-containing microemulsion is found in the specification at page 17, lines 22-23.

New claim 93 reflects subject matter previously recited in claim 1.

New claims 94-98 are directed to the components that make up the resveratrol-containing microemulsion; support for these claims is found in the specification at page 14, line 23 to page 15, line 13.

New claim 99 recites that the pharmaceutical formulation may contain a pharmaceutically acceptable carrier suited for oral or parenteral drug administration; support for this claim is found in the specification at page 17, lines 23-28.

With respect to original claims 69-77, applicant submits that the amendment to independent claim 68 does not render these claims unpatentable because the disclosure at pages 11-

12 regarding the resveratrol active agents is not exclusive to the type of pharmaceutical formulation that the resveratrol will be contained in. With respect to original claims 84-87, the recitation in these claims is supported for oral and parenteral administration because the specification at page 17, line 16-25 provides that the concentrations are preferred for the topical formulations, which include microemulsions, the latter also being useful for oral and parenteral formulations.

No new matter has been added to the application with the amendments set forth herein.

CLAIM REJECTIONS – 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 68-87 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled. The Examiner asserts that the claims, while enabled for treating skin conditions, diseases, and disorders associated with inflammation, does not reasonably provide enablement for preventing skin conditions, diseases, and disorders associated with inflammation. With this response, independent claim 68 has been amended to delete the word “preventing” from the claim. In light of the foregoing, applicants respectfully request reconsideration and withdrawal of this rejection.

CLAIM REJECTION BY CARSON ET AL. UNDER 5 U.S.C. § 102(e)

Claims 68, 73, 74, 79-82, and 84-87 stand rejected under 35 U.S.C. § 102(e) as anticipated by Carson et al. This rejection is moot for canceled claims 79-82 and is respectfully traversed for the remaining claims.

The claimed invention is directed to a pharmaceutical formulation for the treatment of inflammatory skin conditions, disorders, and diseases (claim 68), comprising a therapeutically effective concentration of an active agent selected from the group consisting of resveratrol, pharmacologically acceptable salts, esters, amides, prodrugs, and analogs thereof, and combinations of any of the foregoing, wherein the pharmaceutical formulation is a microemulsion for parenteral administration.

Carson et al. teaches the use of resveratrol for *topical* application to mammalian skin that is dry, flaky, lined, wrinkled, aged, photodamaged, or to healthy skin for prophylactic purposes (col. 3, lines 37-41). Carson et al. also provides that the topical resveratrol may be used for treatment of skin proliferation disorders such as psoriasis or winter xerosis (col. 3, lines 42-44) as well as cosmetic lightening of skin color and to control skin irritation, sting, or inflammation caused by alpha-hydroxy acids (col. 3, lines 49-54; Examples 5, 6 and 7). Carson et al. does *not* teach or suggest that the resveratrol disclosed therein may be administered orally or parenterally or for the inhibition of cellular events associated with tumor initiation.

Because Carson et al. does not teach or suggest the oral or parenteral administration of the resveratrol, it follows that claims 68, 73, 74, 79-82, and 84-87 are not anticipated by Carson et al. Because Carson et al. does not anticipate the claimed invention, applicants respectfully request reconsideration and withdrawal of this rejection.

CLAIM REJECTION OVER CARSON ET AL. UNDER 35 U.S.C. § 103(a)

Claims 68-92 stand rejected under 35 U.S.C. § 103(a) as obvious over Carson et al. This rejection is moot for canceled claims 78-83 and 88-91 and is respectfully traversed for the remaining pending claims, claims 69-77, 84-87, and 91-99.

Carson et al. is described above. With the amendment of the claims from a topical formulation to an oral or parenteral formulation, the claimed invention is not rendered obvious by Carson et al. because Carson et al. does *not* contemplate the oral or parenteral administration of the resveratrol formulation disclosed therein. Because Carson et al. does not teach or suggest oral or parenteral administration of resveratrol, it follows that pending claims 69-77, 84-87, and 91-99 are not rendered obvious by Carson et al. Because Carson et al. does not render the claimed invention obvious, applicants respectfully request reconsideration and withdrawal of this rejection.

CLAIM REJECTIONS OVER ASHIDA UNDER 35 U.S.C. § 103(a)

Claims 69-92 stand rejected under 35 U.S.C. § 103(a) as obvious over Ashida. This rejection is moot for canceled claims 78-83 and 88-91 and is respectfully traversed for all remaining pending claims.


Ashida teaches a cosmetic preparation containing resveratrol that may be useful to prevent skin roughening and molting. Like Carson et al., Ashida does not contemplate oral or parenteral administration of the cosmetic formulation disclosed therein. Because Ashida does not teach or suggest oral or parenteral administration of resveratrol, it follows that pending claims 69-77, 84-87, and 91-99 are not rendered obvious by Ashida. Because Ashida does not render the claimed invention obvious, applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

With the filing of the Request for Continued Examination under 37 C.F.R. § 1.114, applicants respectfully request reversal of the finality of the Office Action under reply. As each of the Examiner's objections and rejections have been addressed and overcome with this Amendment, this application should now be in condition for allowance. Accordingly, applicants respectfully request passage of this application to issue.

Should the Examiner have any questions concerning this response, he is welcome to contact the undersigned attorney at (650) 330-4913 or at canaan@reedpatent.com.

Respectfully submitted,

By: 
Karen Canaan
Registration No. 42,382

REED & EBERLE LLP
800 Menlo Avenue, Suite 210
Menlo Park, California 94025
(650) 330-0900 Telephone
(650) 330-0980 Facsimile

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